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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,222	12/04/2000	Ronald D. Vale	UCSD-04765	3800

7590 12/03/2002
Melden & Carroll
101 Howard Street
Suite 350
San Francisco, CA 94105

EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/03/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/673,222

Applicant(s)

VALE ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 26-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 43-59 is/are rejected.
- 7) ☒ Claim(s) 17-25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Please note the Examiner of record has changed. Contact information is provided at the close of the action.

Election/Restrictions

2. Applicant's election with traverse of Group I (claims 1-25 and 43-59) in Paper No. 15, received September 9, 2002 is acknowledged. The traversal is on the ground(s) that the previous Examiner based the restriction on an erroneous reading of the claims. This is not found persuasive because the first identified group (claims 1-25 and 43-59) lacks a special technical feature because of disclosing references listed in the Election/Restrictions requirement mailed July 5, 2002, hence the group distinction. However, the traversal of the restriction of species i-iii is persuasive and the Examiner has rejoined the species.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-59 are pending.
Claims 26-42, drawn to non-elected inventions are withdrawn from examination.
Claims 1-25 and 43-59 are examined on the merits.

Information Disclosure Statement

4. The information disclosure statement filed May 10, 2002 as Paper number 11 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and

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foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein as references numbered 52-57, 105 and 149 has not been considered. Additionally, Applicants should supply the dates in which the references were published.

Specification

5. The disclosure is objected to because of the following informalities:

(a) on page 18, line 27 there is a period in the midst of a sentence. It is not clear if any another text is missing from the sentence. Applicants are requested to clarify and review the entire specification for similar errors;

(b) it contains an embedded hyperlink and/or other form of browser-executable code on page 8, line 17. Applicant is required to review the entire specification and delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01; and

(c) at several places in the specification there is a colon or a square box after a number, for instance at page 23, line 15; page 45, line 11; page 28, lines 16-17 and 32. Applicant is required to review the entire specification and clarify these markings.

Claim Objections

6. Claims 17, 21, 25, 55, 58 and 59 are objected to because of the following informalities:

(a) Claim 17 contains a grammatical error. The phrase “a microtubules” is not proper. ;

(b) Claims 55 and 59 contain several periods at the end of a claim sentence and within a claim sentence, respectively. It is not clear if any other text is missing from the claims. Likewise, claims 21 and 25 do not contain periods at the end of the claim sentence. Correction is required.;

(c) Claim 58 appears to be missing the recitation “is” between the words “agent” and “one”. Correction is required.; and

(d) Claims 18-20, 23 and 24 are objected to for dependency upon rejected claims 17 and 21.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 2, 4, 9-12 and 55-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 2 and 9 contain acronyms, DAPI, XKCM1 and OP18 that are not well known in the art. Applicants are advised to amend the claims to include the full meaning or identifying characteristics of the abbreviations, such as that listed in claim 3.

b. Claim 53 is indefinite because it references non-elected claim 26. The limitations of claim 26 will be examined in regard to claim 53, however correction is required.

c. Claim 55 is vague and indefinite in the recitation "distinct and distinguishable domain of said array". It is not clear what comprises the domain of the array and what deems it distinguishable. It is not clear what is distinguishable compared to other characteristics of the domain. Applicants are requested to clarify.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 43-46 and 49-54 are rejected under 35 U.S.C. 102(b) as being anticipated by McNally and Vale (Cell 75:419-425, November 5, 1993/ Reference #92 of IDS). McNally and Vale disclose a method of screening for agent that alters microtubule severing by utilizing energy from nucleotide hydrolysis to break tubulin-tubulin bonds within a microtubule polymer, see Abstract on page 419. The agent, named katanin is a heterodimeric protein (60 and 81 kd polypeptides) capable of severing and disassembling microtubules to tubulin dimers, see page 419, Abstract; bridging paragraph of pages 419 and 420. It is reasonable to conclude given identical

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activities that the p60 subunit of katanin disclosed in the McNally and Vale reference is the same as Applicants' SEQ ID NO: 1.

The disclosed method comprised taxol-stabilized fluorescein- and rhodamine-labeled microtubule copolymers in the presence and absence of katanin (p81-p60) and the comparison of fluorescence intensity utilizing fluorescence resonance energy transfer (FRET), see "Tubulin Product..." section of pages 422 and 423 and Figure 5. The contacted labeled tubulin produced by the assay was in the form of tubulin dimers. The assay was performed on a glass coverslip in which the microtubules were immobilized with a microtubule binding protein (MAP), such as *Escherichia coli*-expressed KAR3 protein, see bridging paragraph of pages 427 and 428.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 43-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNally and Vale (Cell 75:419-425, November 5, 1993/ Reference #92 of IDS), in view of Bonne et al. (The Journal of Biological Chemistry 260(5):2819-2825, March 10, 1985). The teachings of McNally and Vale have been presented in the 102(b) rejection. McNally and Vale do not teach that the microtubule of the disclosed method is labeled with 4',6-Diamidino-2-phenylindole (DAPI). However, Bonne teaches that DAPI binds to

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dimeric and to polymeric tubulin and is useful for fluorometric monitoring of microtubule assembly, see page 2819, column 2, paragraph before Materials and Methods section.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize DAPI, a fluorophor for tubulin. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Bonne because DAPI permits a practitioner to follow the kinetics of polymerization *in vitro* and “ [the molecule has] exhibited all the required properties of an extrinsic fluorescent probe toward tubulin.... [such as] its fluorescence was sensitive to environmental conditions; and ...it did not affect the essential features of the macromolecules that were investigated, see page 2824, column 2, first sentence of second paragraph and last paragraph.

13. Claims 43-46 and 49-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNally and Vale (Cell 75:419-425, November 5, 1993/ Reference #92 of IDS), in view of U.S. Patent number 6,083,763 (filed December 31, 1997). The teachings of McNally and Vale have been presented in the 102(b) rejection. McNally and Vale do not teach that the disclosed method is performed in an array, which comprises a microtitre plate and a multiplicity of at least 48 reaction mixtures wherein each reaction mixture comprises a distinct and distinguishable domain of said array with a plurality of agents.

However, U.S. Patent #6,083,763 does teach that a multiplexed molecular analysis system is useful for analyzing and quantifying several molecular targets within

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a sample substance using an array having a plurality of biosites upon which the sample substance is applied, see column 4, lines 30-38. The said system may comprise a microplate based array which can be used for screening analysis, wherein a microplate configured with a four by four (4x4) matrix of biosites in each of the 96 wells would be able to perform a total of 1536 nearly simultaneous tests, see column 4, lines 40-45. The system allows for detecting or the detection of fluorescent labeling, as well as the processing of images to determine information about target molecules within a given sample that leads to analysis output and fast data acquisition, see column 10, lines 17-22; column 27, lines 26-48.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize a multiplexed molecular analysis method comprising a microtitre based array in a method of screening. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of the patent because a multiplexed molecular analysis system can be advantageous due to the commercially availability of reaction vessels such as a microtitre plate which contains at least one reaction chamber, but can contain 8, 24, 96 or 384 reaction chambers. This allows performing in parallel a large set of assays yielding high throughput, low cost, ease in which fluorescent labeling can be modified to achieve the highest signal-to-noise ratio and detection, as well as automated operation, see columns 5 and 6; column 25, lines 26-37.

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14. Claims 43-46, 49-54 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNally and Vale (Cell 75:419-425, November 5, 1993/ Reference #92 of IDS). The teachings of McNally and Vale have been presented in the 102(b) rejection. McNally and Vale do not teach that the disclosed method further comprises listing the agents that alter microtubule polymerization, depolymerization, or severing into a database of therapeutic lead compounds that act on the cytoskeletal system.

However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to comprise a list of molecules that alter the polymerization, depolymerization and severing of microtubules and enter that list of agents into a database or some other form of communication. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success because it would be convenient to provide a listing of agents that alter microtubule polymerization, depolymerization, or severing into database of compounds that act on the cytoskeletal system. The compilation of such compounds would aid a practitioner studying eukaryotic cells to assess molecules involved in the determination of cell architecture, intracellular transport, modulation of surface receptors, mitosis, cell motility and differentiation.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 43-51 and 55-59 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43-71 of copending Application No. 09/724,595 (filed November 28, 2000).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 43-51 and 55-59 of the instant application read on a method for screening for an agent that alters microtubule polymerization, depolymerization or severing, wherein the microtubule depolymerizing protein is selected from the group consisting of katanin, p60 subunit of katanin, XKCM1 and an OP18 polypeptide.

Claims 43-71 of copending application no. 09/724,595 read on a method for screening for an agent that alters microtubule polymerization or depolymerization, wherein the microtubule depolymerizing protein is XKCM1. Said claims from the instant application ('222) are broader in scope than the claims of the copending application ('595), i.e. it does not recite, "severing" in contrast to the instant application. Both sets of claims from the different applications overlap in scope. Claims 43-51 and 55-59 are *prima facie* obvious over copending claims 43-71 in the 09/724,595 application given the microtubule interactions and the depolymerizing proteins of the instant application

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encompass all of the microtubule interactions and proteins presented in the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 43-51 and 55-59 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 51 and 55-66 of copending Application No. 09/724,602 (filed November 28, 2000).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 43-51 and 55-59 of the instant application read on a method for screening for an agent that alters microtubule polymerization, depolymerization or severing, wherein the microtubule depolymerizing protein is selected from the group consisting of katanin, p60 subunit of katanin, XKCM1 and an OP18 polypeptide also art known as stathmin.

Claims 51 and 55-66 of copending application no. 09/724,602 read on a method for screening for an agent that alters microtubule polymerization or depolymerization, wherein the microtubule depolymerizing protein is stathmin, also art known as OP18, see page 4383, column 1, second full paragraph of attached Hunter and Wordeman article (2000). Said claims from the instant application ('222) are broader in scope than the claims of the copending application ('602). The instant application is drawn generically to any protein, hence rendered obvious over application 09/724,602. Both sets of claims from the different applications overlap in scope. Claims 43-51 and 55-59

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are *prima facie* obvious over copending claims 51 and 55-66 in the 09/724,602 application given the microtubule interactions and the depolymerizing proteins of the instant application encompass all of the microtubule interactions and proteins presented in the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

abm 18. Claims 11-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-16 of copending Application No. 09/724,887 (filed November 28, 2000).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 11 and 12 of both applications reference the p60 subunit of katanin having the amino acid sequence of SEQ ID NO: 1. It would have been *prima facie* obvious to one of ordinary skill in the art at the time at the claimed invention was made that the said sequence of both applications would possess the same activity because they are identical. Furthermore, claims 13-16 are drawn to a method performed in array. The limitations of claim 1 (identical in both applications) have been literally incorporated into claim 13 of patent application '887. Claim 13 of patent application '222 depends from claim 1. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the limitations of claim one into claim 13 of patent application '887.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

abn 20. Claims 43-59 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 43-59 of copending Application No. 09/724,596 (filed November 28, 2000). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

abn 21. Claims 1-10 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-10 of copending Application No. 09/724,887 (filed November 28, 2002). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

22. Claims 1-25 are free of the art.

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23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

ALANA HARRIS
PATENT EXAMINER



Alana M. Harris, Ph.D.
December 2, 2002